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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,248	02/13/2001	Robert Amson	065691/0209	2805

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EXAMINER

SCHULTZ, JAMES

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 09/26/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/762,248

Applicant(s)

AMSON ET AL.

Examiner

J. Douglas Schultz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-13, 17 and 18 is/are allowed.
- 6) ☒ Claim(s) 14, 15, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 and 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

File

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

1. Applicant's response filed June 25, 2003 has been considered. Rejections and/or objections not reiterated from the previous office action mailed April 8, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Applicants were correct in presuming that the Office action summary correctly indicated that claims 11-13 are allowable and that 14-16 were rejected under 35 U.S.C. § 112 1st paragraph enablement as reiterated below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Initialed copies of applicants' IDS, form PTO-1449, filed on February 20, 2001, and on April 25, 2001 are being re-sent per applicants' request.

### ***Response to Arguments***

Claims 14, 15, 19, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, and is maintained for the same reasons of record as set forth in the Office action mailed April 8, 2003.

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Applicants' amendment is not considered to overcome the rejection of record, because the amended claims remain broadly drawn to methods of screening for compounds with any type of "memory-restoring activity" in a p53 deficient animal. As indicated in previous Office actions, the term "memory restoring activity" encompasses several distinct aspects of memory formation, including those stored short term, or long term as evidenced in the cited reference of McGaugh et al., (Science, 2000. v287: 248-251). Although applicants have attempted to amend the claims to refer only to "long-term memory", applicants' amended claim language defines such compounds that affect long term memory as "test compounds that improve the diminished capacity to recall the previous test are identified as compounds with long-term memory restoring activity." Since recalling "a previous test" is an event that happens in tests of both short (or working) memory, as well as long term memory, this is not considered sufficient to distinguish short or working memory from long-term memory.

Moreover, applicants' specification does not demonstrate any significant difference in short term memory between any p53 deficient mice and wild type mice. While the specification demonstrates that p53 +/- mice that are taught how to navigate the Morris water maze task do not recall the test as well as wild type mice when tested 15 days later, there is no significant difference between p53 +/- compared to wild type mice when tested in the immediate recall of how to navigate the maze. Moreover, p53 -/- mice never show a significant difference as compared to wild-type in any memory test. Accordingly, while applicant has demonstrated that p53 +/- mice could be used to screen compounds for long term memory enhancement, this demonstration does not provide sufficient guidance to convince one of skill in the art that applicant could screen for compounds in *any* p53 deficient animal to restore any type of memory

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activity, as broadly claimed. See specification, particularly the description of the Morris water maze test and figure 1. In summary, the method as claimed would not distinguish between compounds that affect only long term memory as indicated in applicants response, and accordingly is not considered enabled.

Furthermore, applicants' reference to "memory restoring activity" also directly encompasses another non-enabled screening procedure, namely, testing for compounds that restore specific memories that were once held but were lost over time. Applicants' specification does not provide any description for a screening method that screens for compounds that restore specific memories lost over time. Furthermore, screening methods for such a compound are considered to be unpredictable, because such a compound has yet to be described in the prior art. Accordingly, this aspect of the claimed invention is not considered to be enabled, because such unpredictability would necessarily lead one of skill in the art to engage in undue experimentation to practice the invention over the scope claimed. See M.P.E.P. § 2164.03.

#### *Allowable Subject Matter*

In addition to those claims considered allowable listed above, new claims 17 and 18 are allowed, because the prior art does not fairly teach or suggest using p53 deficient mice to screen for compounds that reduce anxiety, wherein said screening method is an open field test, or wherein said test compound reduces thigmotaxia.

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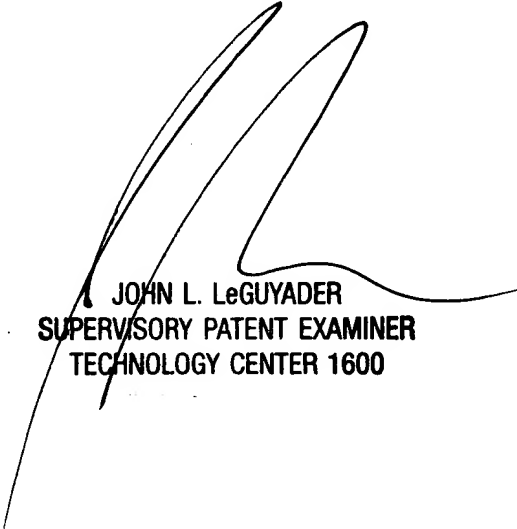
Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355.

The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD



JOHN L. LeGUYADER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600